

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION**

IN RE: DEPUY ORTHOPAEDICS, INC.
PINNACLE HIP IMPLANT PRODUCT
LIABILITY LITIGATION

MDL No. 2244

Honorable Ed Kinkeade

This Document Relates To:

All Cases

**PLAINTIFFS' STEERING COMMITTEE'S PRELIMINARY MEMORANDUM
OF LAW REGARDING BELLWETHER TRIAL PROCEDURE AND SELECTION**

The Plaintiffs' Executive Committee (PEC), on behalf of the Plaintiffs' Steering Committee, respectfully submits this Preliminary Memorandum of Law Regarding Bellwether Trial Procedure and Selection, and in support would show the following:

I. Procedural Background

On September 10, 2013, the parties will attend a status conference to discuss, among other things, the selection of bellwether plaintiffs. Special Master James Stanton instructed the parties to file preliminary briefing on the bellwether trial procedure and their respective candidates by September 2, 2013 (moved to September 3, 2013 by agreement of the parties and with consent of the Special Master).

Defendants have deposed each of the eight bellwether plaintiff candidates, and the parties are working to complete depositions of each plaintiff's revising orthopaedic surgeon – that is, the surgeon who removed the DePuy Pinnacle metal-on-metal hip implant. Because those surgeon depositions will not be complete before the September 10 status conference, the Special Master has informed the parties that additional briefing may be submitted after the bellwether plaintiff discovery is completed.

II. Introduction

"The term bellwether [or early trial case] is derived from the ancient practice of bellng a wether (a male sheep) selected to lead his flock. The ultimate success of the wether selected to wear the bell was determined by whether the flock had confidence that the wether would not lead them astray, and so it is in the mass tort context." *In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig.*, Case No. 00-1898, 2007 WL 1791258, at *1 (S.D.N.Y. June 15, 2007). The goal is to select cases and conduct trials in a manner that will inform and be beneficial to the many thousands of plaintiffs (and their counsel) in this MDL proceeding.

As discussed more fully below, the PEC proposes that the Court conduct an initial bellwether trial that consolidates the claims of six bellwether plaintiffs in a single trial. The consolidated trial would include the cases of the four bellwether plaintiffs selected by the PEC, and the Defendants would be permitted to select two of their bellwether picks for inclusion. This proposal ensures that the September 2014 bellwether trial will truly "lead the flock" by providing guidance to the plaintiffs and counsel in this MDL with respect to their own individual cases. It also represents the most efficient use of time and resources for the parties and, more importantly, the Court.

III. Argument and Authorities – Plaintiffs’ Proposed Bellwether Trial Procedure

A. The Court has broad discretion in its trial selection and management.

The mechanism of bellwether trials can enhance and accelerate both the MDL process itself and the global resolutions that often emerge from that process. "If bellwether trials are to serve their twin goals as informative indicators of future trends and catalysts for an ultimate resolution, the transferee court and the attorneys must carefully construct the trial-selection." Fallon, Grabill & Wynne, *Bellwether Trials in Multidistrict Litigation*, 82 TUL. L. REV. 2323,

2343 (June 2008). However, this careful construction does not demand rigidity. “[T]he sheer number and type of feasible trial-selection processes are limited only by the ingenuity of each transferee court and the coordinating attorneys. . . . [N]o one process is a paragon for all MDLs. Instead, each transferee court that chooses to conduct its own bellwether trials must consider all the unique factual and legal aspects specific to its litigation and then fashion an appropriate, custom-made trial-selection formula.” *Id.* The Court has broad discretion in the management of its trials and in fashioning a trial plan that best serves the interests of all parties and the Court. *See, e.g.,* FED. R. CIV. P. 42(a) (“If actions before the court involve a common question of law or fact, the court may (1) join for hearing or trial any or all matters at issue in the actions; (2) consolidate the actions; or (3) issue any other orders to avoid unnecessary cost or delay.”)

B. An initial trial with six plaintiffs will best promote the purposes of the bellwether trial process.

In addition to the actual selection of bellwether plaintiffs, the Court should also consider the manner in which the bellwether trials should be conducted. The PEC proposes that six plaintiffs’ cases be included and tried in the first bellwether trial. Proceeding with one consolidated trial rather than individual trials is economically efficient and saves the parties and the Court time and resources.

Obviously, no “Pinnacle metal-on-metal” case has ever been tried to a jury, so the verdicts handed down in this first trial, whether favorable or unfavorable to either side, will provide valuable insight to both sides on how the many thousands of cases included in this MDL will have to be resolved. It will enable the parties to consider whether this MDL can and should be resolved by some global resolution mechanism, as is often the case in MDL proceedings, or by hundreds or perhaps thousands of individual trials in the various transferor courts, as DePuy has suggested it intends to address Pinnacle claims. Trying six cases together will best utilize the

Court's and the parties' time and resources, and it will also provide valuable information to the parties, to this Court, and to the transferor courts, about how best to manage this MDL and the many thousands of cases included within it.¹

1. Consolidated trials have been utilized in mass tort litigation.

Federal Rule of Civil Procedure 42(a) grants district courts broad discretion to consolidate cases for trial. As the Mass Tort Litigation Manual notes,

Consolidated trials adjudicating the rights of a few or thousands of plaintiffs can be useful for resolving portions of mass tort litigation. If the consolidated actions involve similar facts and a number of significant common issues, then consolidated trials can be more efficient than individual trials, without imposing on litigant autonomy to the same extent as class actions. In certain mass torts, such as asbestos litigation, it is possible to create groups of plaintiffs with similar or even identical exposure evidence and diagnoses. If such groupings can be accomplished, and the number of plaintiffs kept small enough to allow meaningful participation and to keep the evidence streamlined, consolidated trials enhance efficiency and consistency with little cost to procedural fairness.

Mass Tort Litigation Manual § 6.02[3] (2006). The Court need not look far for examples of courts that have utilized consolidation in the mass tort context:

- *Fraynert v. Delaware and Hudson Railway Co., Inc.*, 2012 WL 6929343 (Pa. Ct. Comm. Pl 2012) (order consolidating for trial actions relating to coal dust and diesel fume exposure)
- *Loewen v. Wyeth, Inc.*, No. 2:03-CV-02166 (N.D. Ala.) (May 12, 2010 order consolidating actions for trial and July 27, 2010 order denying defendants' motion to sever the actions in 2011)
- *Barkley v. United Homes LLC*, No. 1:05-CV-00187 (E.D.N.Y. 2010) (Sept. 13, 2010 order granting plaintiffs' motion to consolidate for trial)

¹ As of August 31, 2013, there are approximately 4,879 cases pending in this MDL, with over 250 new cases filed in or transferred to the MDL in August 2013 alone. DePuy's Pinnacle metal-on-metal hip implants occupied a significant share of the United States hip implant market through 2010, when most orthopaedic surgeons abandoned metal-on-metal hip implants entirely. The PEC anticipates additional claims will continue to be filed in the coming months and years as patients develop problems with their metal-on-metal hip implants, which sometimes take several years to manifest.

- *In re Levaquin Products Liability Litigation*, 2009 WL 5030772 (D. Minn. 2009) (order denying plaintiffs' motion to consolidate for trial three bellwether cases, but indicating the court would reconsider after the close of case-specific discovery)
- *In re Mentor Corp. Obtape Transobturator Sling Products Liability Litigation*, No. 4:08-MD-02004 (M.D. Ga.) (March 3, 2010 order granting Plaintiffs' motion to consolidate for trial)
- *In re New York Asbestos Litigation*, 145 F.R.D. 644 (S.D.N.Y. 1993) (order consolidating 12 asbestos cases for trial)
- *In re Joint Eastern and Southern Districts Asbestos Litigation*, 762 F. Supp. 519 (E.D.N.Y. & S.D.N.Y. 1991) (order denying plaintiffs' motion for a new trial following defense verdict in consolidated trial)
- *In re Fibreboard Corp.*, 893 F.2d 706 (5th Cir. 1990) (order finding "no impediment" to district court's plan to hold consolidated trial on state of the art and punitive damages issues, but vacating order regarding method to determine actual damages)
- *In re Joint Eastern and Southern District Asbestos Litigation*, 1990 WL 4772 (S.D.N.Y. 1990) (order denying motion to sever nine actions consolidated for trial)
- *Johnson v. Celotex Corp.*, 899 F.2d 1281 (2d Cir. 1990) (affirming consolidation of two asbestos cases for trial, *Johnson v. Celotex Corp.*, 89-CV-7484, 89-CV-7542, and *Higgins v. Raymark Industries, Inc.*, 87-CV-0537)
- *In re Joint Eastern and Southern Districts Asbestos Litigation*, 125 F.R.D. 60 (E.D.N.Y. & S.D.N.Y. 1989) (order denying motion to sever four of five cases consolidated for trial)
- *In re Bendectin Litigation*, 857 F.2d 290 (6th Cir. 1988) (order affirming in part, vacating in part judgment for defense in consolidated trial of 818 cases involving birth defects caused by Bendectin ingestion)
- *Neal v. Carey Canadian Mines, Ltd.*, 548 F. Supp. 357 (E.D. Pa. 1988) (order upholding consolidation of 15 claims for trial on liability and damages)

This is just a sample of the courts that have utilized consolidation to assist in the efficient resolution of mass tort cases. The widespread use of consolidated trials should not come as a surprise when consolidation safeguards fairness while minimizing the burden of trial to parties and courts.

2. Consolidating multiple plaintiffs' claims for trial promotes economic efficiency.

Consolidating cases for trial also promotes economic efficiency. It is well known that bellwether trials are incredibly expensive and require massive amounts of time and resources –

from both sides – because the stakes are so high. United States District Judge Eldon Fallon, an experienced MDL judge, accurately described the nature of the mass tort bellwether trial as follows:

[B]ellwether trials are often exponentially more expensive for the litigants and attorneys than a normal trial. This is to be expected to a degree, as coordinating counsel often pull out all the stops for bellwether trials given the raised stakes. For example, in the Vioxx MDL, both sides employed teams of lawyers and utilized jury selection consultants, shadow juries, and mock juries. Live trial testimony was streamed from the courtroom into separate “war rooms” in the courthouse and to remote locations around the country so that attorneys could follow along and, in some instances, draft various motions in real time. All of those bells and whistles add up; indeed holding multiple trials on this stage can quickly swell the cost of multidistrict litigation.

Fallon, Grabill & Wynne, *Bellwether Trials in Multidistrict Litigation*, 82 TUL. L. REV. 2323, 2366 (June 2008). Put candidly, *each* party could easily spend one to two million dollars to try the first case. Thus, it is important that the parties, and the Court, get as much information as possible from their investment. This is best accomplished by consolidating multiple cases in a single trial.

3. A consolidated case best utilizes judicial resources.

Aside from conserving party resources, a consolidated trial will also save scarce and valuable judicial resources. Jury trials utilize a significant amount of judicial resources, not only during the trial itself, but also in the complex and lengthy pretrial proceedings that must occur before the trial can begin. In addition to the time invested by the Judge, court staff also devote significant time and resources to the pretrial and trial process. Conducting one consolidated trial in which six bellwether plaintiffs’ cases are heard will best utilize the Court’s time and resources.

4. A consolidated trial will provide valuable guidance to the Court and the parties on how best to manage this MDL going forward.

Furthermore, the use of a consolidated trial helps promote the progression of the overall MDL. A consolidated trial involving six plaintiffs’ claims will provide the parties with six

individual verdicts for consideration rather than one single verdict. Whether these verdicts are for the plaintiff or the defense, they provide valuable information to both sides on how best to evaluate and manage the thousands of cases pending and to be filed in or transferred to this MDL.

If DePuy intends to defend the Pinnacle cases individually, as it has indicated, the pretrial and trial rulings on the various evidentiary issues, legal issues, motions *in limine*, and other issues in the six selected cases will provide valuable guidance to transferor courts who may have to try Pinnacle cases in the future. In addition, it will also provide an opportunity to tailor the procedures for future, consolidated trials involving multiple plaintiffs' cases. It would be a burden on the various transferor courts to try several thousand individual cases, so consolidated trials will likely be utilized in the future. The information gleaned from a consolidated trial of six bellwether cases will enable this Court to better manage the future course of this MDL proceeding and provide guidance to the parties, their counsel and other courts before whom Pinnacle cases will be heard.

C. Summary – a consolidated trial of six plaintiffs' cases will best utilize the Court's and the parties' resources and will advance the purposes of this MDL.

For the reasons stated, the PEC recommends the Court order a consolidated bellwether trial that will include the cases of six representative plaintiffs – the six bellwether plaintiffs selected by Plaintiffs and two bellwether plaintiffs selected by Defendants. This approach best and most efficiently utilizes the Court's and the parties' substantial amounts of time and resources that will be devoted to the trial. It also provides the Court and the parties with the most information to assist in evaluating how best to manage this MDL proceeding and the many thousands of currently pending and future cases.

IV. Preliminary information on the bellwether trial plaintiffs

The following information is intended to give the Court some basic information on the eight plaintiffs selected as potential bellwethers. All of the plaintiffs have been deposed, and the parties are in the process of completing depositions of their revising surgeons. The information set forth herein comes from their deposition transcripts and medical records, to which both Plaintiffs and Defendants have access.

A. Plaintiffs selected by the PEC

Gerald Jones:

Gerald Jones lives in Dixon, Missouri with his wife, Catherine Jones. He is 57 years old. Mr. Jones enjoys playing golf once or twice a week and also enjoys fishing. Mr. Jones retired from the United States Army after achieving the rank of E-9, Command Sergeant Major, the highest rank possible for a non-commissioned officer. He spends his free time volunteering with the Wounded Warriors program.

Gerald Jones was implanted with a ceramic-on-ceramic hip implant in his left hip in 2001. Mr. Jones experienced no problems with his left hip and continued to serve in the Army from 2001 to 2005, including a deployment to Iraq. When he retired from the Army in 2005, he continued to exercise and enjoyed playing golf seven days a week. Mr. Jones still has the initial implant in his left hip today and has experienced no problems with it.

After his retirement in 2005, Gerald Jones began to experience pain in his right hip. On June 25, 2009, he underwent a total hip arthroplasty surgery on his right hip performed by Dr. Sonny Bal in Columbia, Missouri. Mr. Jones received a DePuy Pinnacle Hip Implant which included a DePuy Pinnacle Sector II Cup, a Pinnacle metal insert, and an Articul/eze M 36mm metal-on-metal femoral head. The stem he received was manufactured by Zimmer, another orthopaedic device manufacturer. Mr. Jones's doctor did not discuss with him the different

materials available to be implanted in his hip prior to the surgery. In fact, Gerald Jones only became aware of the type of implant that was used on his right hip after his revision surgery in 2011.

Beginning in the summer of 2010, Gerald Jones began experiencing severe pain in his right hip. At times the pain was debilitating and required the use of a cane to assist with walking. Due to his symptoms, Dr. Bal recommended a revision procedure. On July 7, 2011, Mr. Jones underwent a right total hip revision procedure. Dr. Bal found “cheesy material” in the hip and a large amount of fluid. He stated in his operative report: “I have seen this many times before. It is a classic metal-on-metal bearing reaction.” Mr. Jones was implanted with a Zimmer metal-on-polyethylene hip implant. Mr. Jones has subsequently undergone a hip aspiration to remove fluid that built up in his hip. Dr. Bal informed him that the fluid build-up could continue from two to four more years, until all of the toxins and metal shavings in his hip dissipate. Gerald Jones continues to experience severe pain in his right hip.

Toni Lay:

Toni Marie Lay is a 65 year old female who lives in Florence, Montana. She and her husband Rondey have been married for 38 years. She has many hobbies, including collecting Santa Clauses, something she has done since she was 17 years old. Toni also loves to ride horses, however has been unable to do this since her hip surgeries. Rondey is retired from the Forest Service, where he served as a “smoke jumper,” a firefighter who jumps into forest fires from airplanes. In 2004, Toni retired from the United States Postal Service, where she served as a Post Master.

Mrs. Lay received her first hip replacement surgery from Dr. David Allmacher in Missoula, Montana on September 11, 2006. Prior to the surgery, she tried non-operative

treatment, but it failed to mitigate her symptoms. Dr. Allmacher replaced her right hip with a DePuy Pinnacle Hip Implant, which included a Pinnacle Sector II cup, a Pinnacle metal liner, an Articul/eze M 36 mm metal on metal femoral head and a Titanium Tri-Lock hip stem.

After Mrs. Lay recovered from her right hip surgery she underwent a left total hip arthroplasty, also performed by Dr. Allmacher, on April 16, 2007. She was implanted with a DePuy Pinnacle Hip Implant, which included a Pinnacle Sector II cup, a Pinnacle metal liner, an Articul/eze 36 mm metal on metal femoral head and a Titanium Tri-Lock hip stem in her left hip.

Mrs. Lay initially did well following her hip replacement surgeries. In 2008, she began to develop pain in her left hip and buttocks. Mrs. Lay underwent blood testing on June 3, 2010, which showed the serum cobalt and chromium levels in her blood were elevated. Dr. Allmacher recommended a revision of her left hip implant. On June 30, 2010 Mrs. Lay underwent a left total hip revision surgery. Dr. Allmacher discovered extensive fluid collection within the hip. He noted “[f]luid was whitish-green in color, consistent with metallosis.” Her Pinnacle metal-on-metal head and liner were removed during this revision procedure. These were replaced with different DePuy Pinnacle components, a metal femoral head and a crosslinked polyethylene liner.

Mrs. Lay began experiencing severe pain in her right hip in 2010. An MRI of her right hip showed large fluid collection in her hip. Dr. Allmacher recommended she undergo a revision surgery based on her history of soft tissue toxicity in her left hip. Mrs. Lay underwent a revision procedure on December 27, 2010. As with her left hip, Mrs. Lay’s Pinnacle metal-on-metal head and liner were removed during this revision procedure. These were replaced with different DePuy components, a ceramic femoral head and a Pinnacle AltrX crosslinked polyethylene liner.

Due to the extensive muscle and tissue loss caused by metal toxicity, Mrs. Lay continued to have problems with her left hip even after the revision surgery. Dr. Allmacher recommended a revision procedure. Mrs. Lay underwent a second revision procedure on April 27, 2011. During this surgery Mrs. Lay was implanted with a mix of Stryker and DePuy components.

Her recovery was further complicated by an infection in her left hip following the second revision surgery. She again returned to surgery on June 28, 2011, where her hip implant was removed and replaced with “antibiotic spacers” to treat the infection. On July 20, 2011 Dr. Allmacher performed another surgery to place antibiotic beads within Mrs. Lay’s left hip. Mrs. Lay was finally able to undergo another revision procedure on May 2, 2012. On that date, the antibiotic spacer and beads were removed and Mrs. Lay was implanted with a Biomet metal-on-polyethylene hip implant.

Carol Mello:

Carol Mello is 61 and resides in Houston, Texas with her husband George Mello. She grew up in Lake Charles, Louisiana and moved to Houston after graduating from college. Mrs. Mello worked as a nurse for a local obstetric/gynecology doctor until she retired in 2011 to spend more time with her family. In her free time she enjoys reading and riding bikes with her husband.

Mrs. Mello underwent a total hip arthroplasty procedure on her left hip in Houston, Texas on April 1, 2005, performed by Dr. Gregory Stocks. Prior to the procedure, the pain in her left hip limited both her activity and her ability to sleep. After consulting with a few doctors for pain treatment, she was referred to Dr. Stocks by her primary care physician. Dr. Stocks diagnosed her with degenerative joint disease and implanted her with a DePuy Pinnacle hip implant, which included a Pinnacle Sector cup, an Ultamet metal liner, an Articul/eze M 36mm metal-on-metal

femoral head and a Summit stem. Dr. Stocks recommended a metal-on-metal implant for Mrs. Mello over a ceramic-on-metal or metal-on-polyethylene implant because he thought it would last the longest, between 20 and 30 years.

After the surgery on her left hip, Mrs. Mello began to experience pain in her right hip. Dr. Stocks performed an x-ray and determined she also needed her right hip replaced due to osteoarthritis. Prior to the procedure, Dr. Stocks again discussed the implant options available to her. Due to longevity, Carol Mello again relied on Dr. Stocks' recommendation of a metal-on-metal implant. On June 23, 2010, she underwent a right total hip arthroplasty performed by Dr. Stocks. She was implanted with a DePuy Pinnacle hip implant, which included a Pinnacle Sector cup, an Ultamet metal liner, an Articul/eze 36mm metal-on-metal femoral head and a Summit stem.

Between 2005 and 2010, Mrs. Mello did not experience any problems with her left hip. In 2010, after her right hip implant surgery, she was able to walk and exercise on a bicycle at the gym. At Carol Mello's one-year follow-up visit after her 2010 surgery, Dr. Stocks ordered a blood test to check her cobalt and chromium levels, which revealed highly elevated levels of serum cobalt and chromium. Dr. Stocks decided to repeat the testing in three months to see if there was any change, but the later test confirmed the elevated cobalt and chromium levels. During this time, Mrs. Mello was not experiencing any pain in her hips, but she did experience a clicking and popping sensation. Dr. Stocks recommended Mrs. Mello undergo revision surgery to remove the metal-on-metal hips. A second opinion was provided by Dr. Melvyn Harrington on December 1, 2011. Dr. Harrington strongly encouraged Mrs. Mello to undergo a revision procedure based on her serum cobalt and chromium levels, fluid collection in her left hip, and crepitus and grinding in her hips.

On December 21, 2011 Carol Mello had surgery to remove both of her Pinnacle metal-on-metal hip implants and replace them with different DePuy Pinnacle metal-on-crosslinked polyethylene hip implants. Dr. Stocks recommended the metal-on-crosslinked polyethylene hip implants because he thought they would last as long as the metal-on-metal devices were supposed to. In describing the procedure, Dr. Stocks noted metallosis was present in both of her hips. Dr. Stocks excised tissue from her right hip that was stained black with metallosis. In the left hip, Dr. Stocks encountered cloudy fluid in addition to tissue stained with metallosis.

Kathleen Herlihy-Paoli:

Kathleen Herlihy-Paoli resides in Missoula, Montana, where she has lived for the past 18 years. She is 57 years old and is married to her husband of 30 years, John Paoli. Mr. Paoli is an architect who designs residential and commercial buildings. Mrs. Paoli is currently self-employed as a graphic designer. In her spare time she enjoys walking, painting, skiing, reading, and fishing.

Mrs. Paoli began having problems with her hips in 2005. The pain progressively got worse, and she decided to undergo a hip replacement surgery when she was no longer able to do activities she enjoyed doing, like skiing and hiking. On October 19, 2009 Mrs. Paoli underwent a right total hip arthroplasty performed by Dr. David Allmacher in Missoula, Montana. Mrs. Paoli discussed various options for the bearing surface with Dr. Allmacher prior to the surgery. Dr. Allmacher recommended that she receive a metal-on-metal hip implant and told her it would be good for 20 to 30 years. Mrs. Paoli was implanted with a DePuy Pinnacle Hip Implant, which included a Pinnacle Sector II cup, a Pinnacle metal liner, an Articul/eze 36mm metal-on-metal femoral head and a Trilock BPS stem in her right hip.

Approximately two months after her right hip replacement, on December 14, 2009, Mrs. Paoli underwent surgery to replace her left hip. Dr. Allmacher replaced her left hip with a DePuy Pinnacle Hip Implant, which included a Pinnacle Sector II cup, a Pinnacle metal liner, an Articul/eze 36mm metal-on-metal femoral head and a Trilock BPS stem. Mrs. Paoli recovered from both hip surgeries with no complications.

Mrs. Paoli began experiencing minor pain with her hip implants in the fall of 2010. On January 4, 2011, Mrs. Paoli underwent blood testing that indicated she had extremely elevated serum cobalt and chromium levels. Dr. Allmacher recommended she be re-tested a month later to confirm the results. On February 7, 2011, her second blood test revealed even higher levels of serum cobalt and chromium. The tests were repeated a third time on March 7, 2011, which again revealed extremely elevated serum cobalt and chromium levels.

On February 23, 2011, Mrs. Paoli underwent an MRI on her left hip that showed a fluid collection and soft tissue particle disease. Due to the persistently elevated metal levels in her blood and the MRI results, Dr. Henrik Malchau, a Harvard medical school orthopaedic surgery professor, recommended a revision surgery on her left hip. Blood testing was again performed a week before she underwent a revision procedure on her left hip, which again revealed very elevated cobalt and chromium levels. Dr. Malchau revised Ms. Paoli's left hip on April 26, 2011, at Massachusetts General Hospital in Boston. During the surgery, Dr. Malchau discovered copious amounts of bluish green fluid in her hip. In his Operative Report Dr. Malchau stated: "[t]here was obvious metallosis and metal staining throughout the area." During the surgery, the Pinnacle metal liner and Articul/eze metal on metal femoral head were removed. Mrs. Paoli was implanted with different Pinnacle components: a Pinnacle AltrX polyethylene liner and an Articul/eze 36mm femoral head.

Following revision on her left hip, Mrs. Paoli continued to undergo monthly blood testing. Those tests continued to reveal elevated cobalt and chromium levels. An MRI of her right hip also showed effusion of the hip. Due to this finding and the still-elevated blood levels, Dr. Malchau recommended that Mrs. Paoli undergo a revision procedure on her right hip, which was done on November 8, 2011. During this surgery Dr. Malchau encountered metallic-colored gray fluid. He again found “obvious metallosis and metal staining.” Mrs. Paoli was implanted with Biomet and DePuy components during this procedure.

Following the two revision surgeries, Ms. Paoli continued to have blood testing, which revealed a decrease in serum cobalt and chromium levels. MRIs of both hips taken on September 24, 2012 show that fluid is no longer collecting in her hip areas.

B. Plaintiffs selected by DePuy

Jean Garvin:

Jean Garvin is 61 years old and resides in Dubois, Pennsylvania with her husband of 42 years, Vaughn Garvin. Her husband is a behavior health technician at Dubois Regional Medical Center. Mr. and Mrs. Garvin have three adult children. Jean has taught a Bible study for a number of years and enjoys reading the Bible on a daily basis. She also enjoys crocheting and solving puzzles to keep her mind stimulated.

Mrs. Garvin began experiencing problems in her right hip at the beginning of 2010. She decided to undergo a hip replacement surgery because her surgeon, Dr. Keith Zeliger, recommended it. Mrs. Garvin did not discuss the materials in the implant with Dr. Zeliger prior to the surgery. Dr. Zeliger only told her he was going to use a device that was long lasting. Mrs. Garvin underwent a right total hip arthroplasty on December 8, 2010, at the DuBois Regional Medical Center. She was implanted with a DePuy Pinnacle Hip Implant, which included a

Pinnacle 300 cup, a Pinnacle metal liner, an Articul/eze 36mm metal-on-metal femoral head and a Corail stem in her right hip.

In the year and a half following her hip surgery, Mrs. Garvin battled with dislocations of her hip. On multiple occasions she required hospitalization to reduce her hip back into place. On May 15, 2012 Mrs. Garvin underwent revision surgery performed by Dr. Charles Spingola. Her Pinnacle metal-on-metal hip implant was removed and replaced with a different DePuy Pinnacle hip implant, one with a metal femoral head and crosslinked polyethylene liner.

Michael Hodges:

Michael Hodges is a 50 year old male who has lived in Trenton, New Jersey his whole life. He is engaged to Janet Smith and has three children. Prior to experiencing hip problems he enjoyed playing basketball.

In 2006, Mr. Hodges began to experience pain in his left hip. He was initially treated by his primary care physician but was referred to an orthopaedic surgeon, Dr. Edward Ford. Dr. Ford recommended he receive a total hip arthroplasty to replace his left hip. On June 9, 2006, Michael Hodges underwent a total hip arthroplasty surgery in Trenton, New Jersey. He was implanted with a DePuy Pinnacle Hip Implant, which included a Pinnacle cup, an Ultamet metal liner, an Ultamet Articul/eze M 36mm metal-on-metal femoral head and an AML femoral stem. Mr. Hodges was not aware that he received a metal-on-metal hip until recently.

Mr. Hodges initially did well following his hip replacement surgery. Beginning in 2009, however, he began to experience pain in his hip. On May 11, 2009, Mr. Hodges consulted with Dr. Mark Pressman, another orthopaedic surgeon. During the consultation, he had fluid removed from his hip and sent to the laboratory. The fluid came back negative for a staph infection. The pain continued, and on July 22, 2009 Mr. Hodges underwent surgery to remove his left hip implant. On that date, Dr. Pressman removed his hip and implanted a temporary antibiotic

spacer. In his operative report Dr. Pressman noted that there was a small amount of fluid in the joint. Bone and tissue cultures were sent to the laboratory for testing. The bone and tissue samples tested for infection all came back negative.

On November 16, 2009 Mr. Hodges returned to surgery to have the antibiotic spacer removed and replaced with another permanent hip implant. Dr. Pressman removed the antibiotic spacer and implanted another DePuy Pinnacle metal-on-metal hip implant, which included a Pinnacle Sector II cup, a Pinnacle metal liner, an Articul/eze M-Spec metal-on-metal femoral head and a DePuy Solution Stem in his left hip.

Edward McKee:

Edward McKee is 46 years old and resides in Iowa City, Iowa with his wife Natasha McKee. Prior to moving to Iowa in 2010, Mr. McKee lived in Chicago his entire life. Edward and Natasha have four children. At the age of 8, Mr. McKee underwent surgery to place a plate and screws in his right hip after being hit by a car.

Mr. McKee began having problems with his right hip in 2006. He was no longer able to play basketball or ride his bicycle. On March 21, 2008, Dr. Hue Luu performed a right total hip arthroplasty procedure at the University of Chicago Medical Center. Mr. McKee received a DePuy Pinnacle Hip Implant which included a DePuy Pinnacle Multihole II Cup, a Pinnacle metal insert, an S-Rom metal-on-metal femoral head and an S-Rom stem. Edward McKee remained pain free following his hip replacement for six months.

In 2009, Mr. McKee began experiencing severe pain his hip which resulted in visits to the emergency room. Dr. Charles Clark recommended a revision procedure. Mr. McKee underwent a revision procedure on September 15, 2010, in Iowa City, Iowa. During the revision procedure performed by Dr. Clark, Mr. McKee had his metal femoral head and stem exchanged.

Mr. McKee was again implanted with DePuy Pinnacle metal-on-metal hip implant components: a DePuy Total Hip Solutions stem and an Articul/eze metal on metal femoral head. Mr. McKee had no input on the products that were implanted during the revision procedure. Two weeks after the revision procedure, Mr. McKee returned to the hospital with an infection in his hip. He continues to suffer from pain in his hip joint.

Byron Rowe:

Byron Rowe is 52 years old and resides with his wife Melanie in Orange Park, Florida. Melanie is a sixth grade math and social studies teacher. Byron and Melanie have three grown children who are all currently attending college. Mr. Rowe is a retired corpsman from the United States Navy. He was deployed to Iraq in 2004.

Mr. Rowe was on active-duty status when he underwent a right total hip arthroplasty on June 23, 2006. His symptoms prior to the surgery were pain, walking with a limp and decreased activity. The procedure was performed by Dr. David Whiddon at the Naval Medical Center in Portsmouth, Virginia. Mr. Rowe selected a metal-on-metal hip implant because he believed it would be stronger than a metal-on-ceramic implant. His physicians did not recommend he receive an implant other than a metal-on-metal implant. Mr. Rowe received a DePuy Pinnacle Hip Implant which included a DePuy Pinnacle Sector II Cup, a Pinnacle metal insert, an Articul/eze M 36mm metal-on-metal femoral head and a Summit stem.

Following the implantation of his right hip, Mr. Rowe initially did well. Approximately two years later, beginning in the summer of 2008, he experienced some aches and pains in his hip. On August 24, 2008 Mr. Rowe went to the emergency room in excruciating pain. He was admitted to the Naval Hospital in Jacksonville, Florida with a fever of 102 degrees and an elevated white cell count. Mr. Rowe had some dental work done a few days before without

utilizing prophylactic antibiotics, and the Naval Hospital doctors suspected an infection in his hip and recommended a revision surgery. Mr. Rowe did not select the type of device to be utilized during his revision surgery, rather, the decision was left up to the surgeon, Dr. Emeka Ofobike. Dr. Ofobike removed Mr. Rowe's metal femoral head and liner and replaced them with similar Pinnacle metal-on-metal implant components – a Pinnacle metal insert and an Articul/eze M 36 mm metal on metal femoral head.

During the revision procedure, Dr. Ofobike encountered a “pocket of pus” in Mr. Rowe's hip. Three swabs fluid were sent to the laboratory to determine if there was an infection, but the laboratory reported no bacterial growth from the cultures, indicating there was no infection in Mr. Rowe's hip.²

IV. Conclusion and Prayer

For the reasons stated herein, the PEC respectfully requests that the Court enter an order regarding the bellwether trial scheduled for September 2014 that (1) selects the cases of Gerald Jones, Toni Lay, Carol Mello, and Kathy Herlihi-Paoli for trial; (2) authorizes Defendants to select two of their four bellwether plaintiffs' cases for trial; and (3) consolidates all six plaintiffs' cases for a trial to begin in September 2014. The PEC respectfully reserves the right to supplement this submission once the bellwether discovery process has been completed, or as circumstances may warrant.

² One of the frequently reported problems encountered by patients who receive metal-on-metal hip implants is a collection of fluid in the hip joint area that is often described by the revising surgeons as cloudy, yellow or gray. Sometimes this fluid can be aspirated from the joint, and it is often encountered during revision surgery. Many orthopaedic surgeons now use the term “pseudotumor” to describe this condition, but it was not very well understood in 2008 and surgeons often thought they were dealing with an infection of the hip joint rather than a soft tissue response to metal debris.

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Respectfully submitted,

/s/ Larry P. Boyd

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*Plaintiffs' Executive Committee on behalf of the
Plaintiffs' Steering Committee*

CERTIFICATE OF SERVICE

I certify that this document was served on all counsel of record by the Court's CM/ECF system, and was also forwarded to counsel for the DePuy Defendants by electronic mail, on September 3, 2013.

/s/ Larry P. Boyd
Larry P. Boyd